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APPLICATION NO.	F	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/601,032	06/20/2003		David J. Hammond	222363	5177
23552	7590	08/03/2006		EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903				STEELE, AMBER D	
MINNEAPOLIS, MN 55402-0903				ART UNIT	PAPER NUMBER
	,			1639	
				DATE MAIL ED: 08/03/200	6

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Office Action Comment	10/601,032	HAMMOND ET AL.					
Office Action Summary	Examiner	Art Unit					
	Amber D. Steele	1639					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 10 Ma	Responsive to communication(s) filed on 10 May 2006.						
· · · ·							
3) Since this application is in condition for allowan	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims		•					
4)⊠ Claim(s) <u>1-27</u> is/are pending in the application.							
	4a) Of the above claim(s) <u>7-10,13,16,17 and 25-27</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6) Claim(s) 1-6, 11-12, 14-15, and 18-24 is/are re							
7) Claim(s) is/are objected to.	•						
8) Claim(s) are subject to restriction and/or							
Application Papers							
9) ☐ The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:	a) ☐ All b) ☐ Some * c) ☐ None of:						
<ol> <li>Certified copies of the priority documents</li> </ol>	s have been received.						
<ol><li>Certified copies of the priority documents</li></ol>							
<ol><li>Copies of the certified copies of the prior</li></ol>	•	ed in this National Stage					
application from the International Bureau	,						
* See the attached detailed Office action for a list of	of the certified copies not receive	d.					
Attachment(s)	. 🗖 .						
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date							
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) 🔲 Notice of Informal P	atent Application (PTO-152)					
Paper No(s)/Mail Date 6)  Other:							

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### **DETAILED ACTION**

## Status of the Claims

1. Claims 1-27 are pending.

Claims 1-6, 11-12, 14-15, and 18-24 are currently under consideration.

#### Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-24) in the reply filed on May 10, 2006 is acknowledged. The traversal is on the ground(s) that a search burden does not exist. This is not found persuasive because these inventions are distinct and: A. have acquired a separate status in the art as shown by their different classification (Group I claims 435, subclass 4; Group II class 530, subclass 412; Group III class 536, subclass 127), and/or B. divergent subject matter which would require different bibliographic and/or classification searches; and/or C. because the inventions have acquired a separate status in the art because of the recognized divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

- 3. Claims 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

  Applicant timely traversed the restriction (election) requirement in the reply filed on May 10, 2006.
- 4. Applicant's election of peptide as the species of ligand, polymethacrylate as the species of support, conditioned cell medium as the species of mixture/composition, protein as the species

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of entity, and cell proliferation as the species of activity in the reply filed on May 10, 2006 is acknowledged. The traversal is on the ground(s) that "Applicants take no position regarding whether the claims of the various groups and species identified in the Official Action define distinct inventions". This is not found persuasive because applicants have not specifically pointed out the reasons for the traversal therefore the traversal is moot. The requirement is still deemed proper and is therefore made FINAL.

5. Claims 7-10, 13, and 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 10, 2006.

## Claim Interpretation

6. The presently claimed invention is directed to:

A screening method comprising:

- i. providing a plurality of ligands attached to a support,
- ii. contacting the ligand-support complexes with a mixture of entities to form entity-ligand-support complexes,
  - iii. separating nonbound entities form the complexes,
  - iv. assaying for an activity,
  - v. detecting the activity, and
  - vi. selecting an entitiy-ligand-support complex.

## Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 11-12, 14-15, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Todara U.S. Patent 4,816,561 issued March 28, 1989.

For present claims 1 and 18, Todara teaches a method of screening aqueous solutions for polypeptides (e.g. active entities) via providing antibodies or antigens attached to supports (e.g. ligand-support), contacting the antibodies or antigens on the supports with cells expressing TGF polypeptide (e.g. entity-ligand-support), separating the cells with a fluorescence activated cell sorter, assaying for cell growth, detecting cell growth, and selecting the molecule with activity or via HPLC columns (e.g. ligands-supports wherein ligands are for example hydrophobic alkyl chains), contacting aqueous heterogenous solutions with peptides of TGF (e.g. mixture with plurality of entities), separation, assaying for cell growth, detecting cell growth, and selecting TGF or TGF peptides (please refer to abstract; columns 5 and 10-16; Examples I-XV; Tables I-IX).

For present claim 2, Todara teaches that the ligands can be proteins, peptides, synthetic organic compounds (e.g. HPLC columns with hydrophobic alkyl chains; please refer to columns 4-6 and 14).

For present claim 3, Todara teaches that peptides can be generated by synthetic techniques, hybrid DNA technology techniques (e.g. combinatorial approaches; please refer to column 10).

For present claim 4, Todara teaches that the support can be an HPLC column (e.g. with silica/silicon), a solid support (e.g. beads = silicon; plates = polystyrene, etc.), polystyrene resin supports, or agar/agarose (please refer to columns 10, 12-14; Examples I-II).

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For present claims 5-6, Todara teaches that a heterogenous aqueous solution including serum-free medium conditioned by various cells, urine, serum, plasma, whole blood, or cerebrospinal fluid can be utilized in the methods (please refer to columns 5 and 10-11;

Examples I-II, XI).

For present claim 11, Todara teaches that the desired products in the solutions (see above for claims 5-6) can be polypeptides (e.g. proteins) or peptides (please refer to columns 6-10).

For present claims 12 and 14-15, Todara teaches that the polypeptides or peptides can be screened for activities including cell proliferation and EGF binding (please refer to columns 11-12; Examples I-II).

For present claim 20, Todara teaches chemical synthesis and characterization of peptides (e.g. chemical identity; please refer to Examples V, XI, and XV).

Therefore, the presently claimed invention is anticipated by the teachings of Todara.

9. Claims 1-6, 11-12, 14-15, 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al. U.S. Patent 5,510,240 issued April 23, 1996.

For present claims 1 and 18, Lam et al. teach methods of screening peptide libraries via library of bio-oligomers (e.g. peptides) attached to solid phase supports (e.g. ligand-support), introducing an acceptor molecules or substrate molecule (e.g. protein) that recognizes and binds the solid phase support-bio-oligomer (e.g. entity-ligand-support), washing nonbound molecules from the mixture, assaying for binding or chemical reaction, detecting binding or the chemical reaction, and isolating a support/bio-oligomer/molecule with the desired property including

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binding, stimulation, inhibition, toxicity, etc. (e.g. activity) (please refer to abstract; sections 1, 3, 5.1, 5.4, 5.5 including 5.5.1-5.5.3; Example sections 6-14; Figures 1-2 and 4-8D).

For present claims 2-3, Lam et al. teach that the ligands can be peptides or nucleic acids (please refer to sections 5.1, 5.2, 5.3).

For present claim 4, Lam et al. teach that the supports can be silica, resin, plastic films, glass beads, alumina gels, polystyrene, polydimethylacrylamide (e.g. polymethacrylate; please refer to section 5.4).

For present claims 5-6, Lam et al. teach that the cells and conditioned culture medium can be utilized in the screening methods (please refer to sections 5.5.2.1).

For present claim 11, Lam et al. teach that the molecule (e.g. entity) can be protein, antibody, enzyme, cell, receptor, virus, carbohydrate, drugs, lipids (please refer to sections 5.5, 5.5.1).

For present claims 12 and 14-15, Lam et al. teach determining activities including binding, stimulation, inhibition, toxicity, enzyme activity, killing, growth promotion, physiological change (please refer to sections 5.5 including 5.5.1, 5.5.2).

For present claim 19, Lam et al. teach that the beads can be partitioned and separated into smaller pools (e.g. subpools; please refer to sections 5.5.1, 5.5.2).

For present claims 20 and 23, Lam et al. teach identifying peptide sequences including sequencing (please refer to section 5.5.2; Tables 1-5; Examples 10-13).

For present claims 21 and 22, Lam et al. teach that the screening assay can repeated several times and that cleavable linkers can be utilized to recover the peptides bound to the supports (sections 5.1, 5.5.1, 5.5.2, 5.4).

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For present claim 24, Lam et al. teach that cleavage and/or release of the components of

the molecule-peptide-support is possible (please refer to 5.1, 5.5.1, 5.5.2, 5.4).

Therefore, the presently claimed invention is anticipated by the teachings of Lam et al.

Future Communications

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The

examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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like assistance from a USPTO Customer Service Representative or access to the automated

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information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ADS July 18, 2006